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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,042	01/21/2004	Jei-Fu Shaw	08919-099001 / 09A-910930	3786
26161	7590	02/13/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			KUMAR, VINOD	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/763,042

Applicant(s)

SHAW ET AL.

Examiner

Vinod Kumar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 9, 11, 13 and 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-8, 10, 12, 14 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <del>10-26-04</del> <u>10-26-04</u>  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's election without traverse of Group II, claims 6-8, 10, 12, 14 and 22-25 and the nucleotide sequence set forth in SEQ ID NO: 20, and the species plant in the paper filed on December 5, 2005 is acknowledged. As claim 7 is shared between Groups II and III, the claims of Group III are rejoined with Group II and examined together on merits. Accordingly, claims 1-5, 16-21 and SEQ ID NOs: 1-8, 10-19, 21 and 22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Elected claims must be amended to remove non-elected subject matter. This restriction is made FINAL.

### ***Information Disclosure Statement***

2. An initialed and dated copy of Applicant's IDS form 1449 is attached to the instant Office action.

### ***Specification***

3. The abstract of disclosure is objected to because of the following informalities:

In lines 5 and 7, "SEQ ID NOs:1-11" are polypeptides and should be replaced by --SEQ ID NOs: 20--, which is the elected nucleotide sequence. The Abstract should be limited to the elected sequence. Also the first sentence of the Abstract is incomplete.

Appropriate corrections are required.

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded

hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 18, line 15, and page 19, line 21.

Appropriate corrections are required.

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. For example, Sequence identifiers are missing from page 26, lines 3-6.

If the sequences appearing in the specification do not have sequence ID numbers assigned to them, then an amendment to the sequence listing will be required as well. There must not be any new matter submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification.

Appropriate corrections/clarifications are required.

### ***Claim Objections***

6. Claims 6, 8, 10, 14, and 25 are objected to because of the following informalities:

Claims 6, 8, 10, 12 and 14 are objected to for depending from non-elected claim.

In claims 8-11, the recitation "a nucleotide" should be replaced by --the isolated nucleic acid--.

In claim 25, the recitation "generate" in line 5 should be replaced by --regenerate--.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 25 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification describes that over-expression of AtLPs that encompass SEQ ID NO: 9, increases sensitivity of the plant to various environmental stresses. See Page 12, lines 14-15 of specification. It is well established in the art that sensitivity of a plant to various environmental stresses can drastically reduce crop productivity. Thus the claimed method of producing a transgenic plant expressing SEQ ID NO: 9 does not appear to have any use in the real world. Accordingly, the claimed method of expressing a recombinant nucleic acid encoding a heterologous polypeptide of SEQ ID NO: 9 in a transgenic plant lacks substantial utility.

Claim 25 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards the invention.

Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the article "a" in "a heterologous polypeptide of SEQ ID NO: 9", which is confusing as it encompasses any subsequence within SEQ ID NO: 9. It is suggested to replace "a" with --the--.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising a sequence that encodes a polypeptide SEQ ID NO: 9, does not reasonably provide enablement for a nucleic acid that encodes for a polypeptide having at least 70% but less than 100% sequence identity with SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims are broadly drawn to an isolated nucleic acid encoding a polypeptide that is at least 70% identical to SEQ ID NO: 9 or wherein said isolated nucleic acid under

high stringency condition hybridizes to a probe containing a sequence of SEQ ID NO: 9 or complement thereof.

The specification describes isolation of *Arabidopsis* nucleic acid sequences encoding for tubby-like proteins (AtLPs) using gene-specific primers in PCR reactions. The isolated sequences are defined in SEQ ID NOs: 12-22. See Page 15, Table 1; Page 16-18. The specification also describes expression of AtLP genes in different tissues of *Arabidopsis*. See Page 19.

The Claim 6 encompasses the polypeptide sequences that are at least 70% but less than 100% identical to SEQ ID NO: 9 and the claim 7 encompasses nucleic acid sequences that would hybridize with any subsequence of SEQ ID NO: 20.

Guo et al. (PNAS, 101: 9205-9210, 2004) teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as 70% would encompass more than single amino acid changes of the encoded polypeptide as defined in SEQ ID NO: 9.

There is a lack of specific guidance in the specification as to how any nucleic acid encoding for a polypeptides that is at least 70% but less than 100% identical to SEQ ID NO: 9 can be used in a method to produce a product with function identical to SEQ ID NO: 9. Undue experimentation is required by a skilled artisan to determine how a nucleic acid comprising a sequence encoding a polypeptide that is not identical to SEQ ID NO: 9 can be used in any method that produces the product with a function identical to a nucleic acid comprising a sequence encoding the polypeptide as defined

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in SEQ ID NO: 9. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Claims 10, 11 and 14 encompass any host cell transformed with a nucleic acid sequence encoding a polypeptide as defined in SEQ ID NO: 9. The specification does not describe the use of transforming a host cell other than bacteria or plant cell with a nucleic acid sequence encoding said polypeptide. Undue experimentation by one skilled in the art is required to make use of expressing a said polypeptide in a host cell other than bacteria or plant cell, as SEQ ID NO: 9.

Given the breadth of the claims, unpredictability of the art and lack of guidance in the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use of claimed invention. Therefore, it is maintained that the claims are not commensurate in scope with the teachings of the specification.

10. Claims 6-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to an isolated nucleic acid encoding a polypeptide that is at least 70% identical to SEQ ID NO: 9 or wherein said isolated nucleic acid under high stringency condition hybridizes to a probe containing a sequence of SEQ ID NO: 9 or complement thereof.



The specification describes isolation of *Arabidopsis* nucleic acid sequences encoding for tubby-like proteins (AtLPs) using gene-specific primers in PCR reactions. The isolated sequences are defined in SEQ ID NOs: 12-22. See Page 15, Table 1; Page 16-18. The specification also describes expression of AtLP genes in different tissues of *Arabidopsis*. See Page 19.

The Claim 6 encompasses the polypeptide sequences that are at least 70% but less than 100% identical to SEQ ID NO: 9 and the claim 7 encompasses nucleic acid sequences that would hybridize with any subsequence of SEQ ID NO: 20. The specification does not describe the structure of such sequences, and further fails to disclose the structure function relationship of such sequences. The specification does not correlate the structures of different species of the broadly claimed genus to a common function. The Federal Circuit provided the appropriate standard for written description in University of California v. Eli Lilly & Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court held that a structural description of a rat cDNA was not an adequate description of broader classes of cDNAs, because a "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subjected matter sufficient to distinguish it from other materials.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 6-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Lin et al. (NCBI, GenBank, Sequence Accession No: AC011623, Pages 1-37, Published October 2002).

The claims are drawn to an isolated nucleic acid that encodes a polypeptide as defined in SEQ ID NO: 20, or an isolated nucleic acid that under a high stringency condition hybridizes to a probe containing a sequence as defined in SEQ ID NO: 20 or a complement thereof, or a vector comprising said nucleotide sequence.

Lin et al. teach isolation and sequencing of a DNA which comprises the nucleotide sequence (positions 54079-55912) of a BAC clone having 100% sequence identity with SEQ ID NO: 20 of instant application. The nucleotide sequence from positions 54079-55912 of reference encompass instant SEQ ID NO: 20, encoding instant SEQ ID NO: 9, which is also a part of an expression vector BAC clone. Page 9 of reference teaches the coding region of the genomic clone comprising cDNA that is 100% identical to SEQ ID NO: 20 and encoding a protein having 100% sequence identity with SEQ ID NO: 9. Also see pages 28-29 of reference. BAC clone taught in the reference is an expression vector. The property of hybridization of a probe

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containing SEQ ID NO: 20 sequence or a complement thereof to an isolated nucleic acid is inherent to the sequence taught in the reference.

Accordingly, Lin et al. anticipated the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 6-<sup>15</sup>~~14~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (NCBI, GenBank, Sequence Accession No: AC011623, Pages 1-37, Published October 2002) and further in view of Maniatis et al. (Cold Spring Harbor Laboratory, Chapter 12, Pages 404-421, New York, 1982).

The claims are broadly drawn to an isolated nucleic acid that encodes a polypeptide as defined in SEQ ID NO: 9, or an isolated nucleic acid that under a high stringency condition hybridizes to a probe containing a sequence as defined in SEQ ID NO: 20 or a complement thereof, or a vector comprising said nucleotide sequence, wherein a host cell comprises said vector, or a method of producing a polypeptide by expressing said polypeptide in a host cell comprising said vector.

Lin et al. teachings are discussed as supra.

Lin et al. do not teach a method of producing a polypeptide in a host cell.

Maniatis et al. teach a method of expressing and isolating a protein from a bacterial host cell comprising an expression vector comprising a nucleic acid sequence of interest. See the entire article.

It would have been obvious to one of ordinary skill in the art to use the method of Davis et al. in expressing the polypeptide taught by Lin et al. in *E. coli*, and isolating it. One of ordinary skill in the art would have been motivated to do so for the purpose of protein characterization.

### ***Conclusions***

13. No claims are allowed.

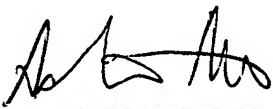
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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**ASHWIN D. MENTA, PH.D.**  
**PRIMARY EXAMINER**